REMARKS

Reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. SUPPORT FOR AMENDMENTS (35 USC § 112)

Claim 16 has been amended as follows:

"16. (Currently amended) Self-supporting films as claimed in claim 1, also containing ~~other~~ excipients selected from the group consisting of anticaking agents, sweeteners, flavourings, colouring agents, preservatives, acidity regulating systems and mixtures thereof."

In amended Claim 16, the term "other" which was rejected under § 112, has been deleted, in order to clarify that the films of claim 1 can also include excipients.

Therefore, the rejection of claim 16 under 35 U.S.C. 112, second paragraph, in the outstanding Office Action has been overcome and should be withdrawn.

In the outstanding Office Action, Claim 1 has been rejected under 35 USC §112, 2nd paragraph, since the Examiner has alleged that "maltodextrin is known in the art as a hydrocolloid", whereas by the "art" the Examiner means paragraph [0059] of Chen et al. (US 2003/0068378).

In Applicants' previous response of August 9, 2010, a wide-ranging discussion was provided about hydrocolloids. Particularly, **Annex A** (a presentation of Timothy J. Foster, who is Associate Professor and Reader in Food Structure, Faculty of Science, at the University of Nottingham (UK) and **Annex B** (an extract from *Handbook of hydrocolloids*, Glyn O. Phillips, Peter A. Williams; Woodhead Publishing Ltd, 2000) clearly demonstrated that hydrocolloids do not encompass maltodextrin.

However, in order to make this point definitely clear, Applicants hereby submit **Annex C**, which is a second extract from the same *Handbook of hydrocolloids*, wherein the following sections have been provided:

- "Contents": the index of subsections of the handbook itself, where all the hydrocolloids are listed, each of them discussed by key experts;

- "Contributors": the index of said key experts;

- page 3, where in Table 1.2, the hydrocolloids are listed along with their function; and

- the back cover, where it is declared that "the handbook is "Edited by two of the leading international authorities in the field, with contributions from key experts". The authors, i.e. Prof. G.O. Phillips and Prof. P.A. Williams, "are internationally recognized experts on hydrocolloids" and "Directors of Food Hydrocolloids Trust".

It can immediately be seen that maltodextrin is nowhere counted or enumerated among hydrocolloids in the Contents of the above handbook, which is also in accordance with **Annex B**. Thus, maltodextrin is not a hydrocolloid as acknowledged by all the internationally recognized experts.

The Examiner makes reference to paragraph [0059] of Chen et al., reciting:

> of 2 mil. In embodiments of the invention, the hydrocolloid may be a water soluble non-gelling (at room temperature) natural polysaccharide or derivatives including pectin and derivatives, guar gum arabic, tragacanth gum, xanthan gum, gellan sodium salt, propyleneglycol alginate, starches (amylose, amylopectin), modified starches, hydroxyethyl starch, pullulan, carboxymethyl starch, gum ghatti, okra gum, karaya gum, dextrans, dextrins and maltodextrins, konjac, acemannan from aloe, locust bean gum, tara gum, quince seed gum, fenugreek seed gum, scleroglucan, gum arabic, psyllium seed gum, tamarind gum, oat gum, quince seed gum, carrageenans, scleraglucan, succinoglucan, larch arabinogalactan, flaxseed gum, chondroitin sulfates, hyaluronic acid, curdlan, chitosan, deacetylated konjac, and rhizobium gum.

Firstly, it can be noted that this paragraph ***improperly*** includes maltodextrins among hydrocolloids.

Secondly, it states that "the hydrocolloids may be a water soluble non-gelling (at room temperature) natural polysaccharide or derivatives including ..." [emphasis added]. However, this is a further error since a number of the listed compounds are gelling

hydrocolloids, as listed in Table 1.2 of Annex C. The skilled artisan would thus know that the definition provided by Chen et al. is, at a minimum, contradictory and incorrect.

Additionally, maltodextrins are also listed, within the same document, on paragraph [0043] as inert filler:

> **[0043]** Water soluble inert fillers include mannitol, xylitol, sucrose, lactose, maltodextrin, dextran, dextrin, modified starches, dextrose, sorbitol, and dextrates. The water soluble inert fillers may be used in embodiments of the invention as inert carriers to form a high water soluble dispersion with active agents.

In view of what has been said above and having knowledge of the given state of the art about hydrocolloids, a skilled person would and necessarily be led to disregard the teaching of Chen et al. as ***unreliable prior art.***

The Examiner himself provides a further confirmation of the foregoing, when he cites Zych et al. (US2003/0054039) in the outstanding Office Action. As a matter of fact, Zych et al. discloses an edible film comprising a maltodextrin, a hydrocolloid and a filler, thus acknowledging a ***clear distinction*** between ***maltodextrin and hydrocolloids***.

At paragraphs [0026-0030], maltodextrin are defined, whereas at paragraph [0031], hydrocolloids are discussed and compounds falling within this category are listed, as follows:

> **[0031]** The hydrocolloid can provide thickness and decrease brittleness of the edible films. The hydrocolloid can include any suitable type, amount and number of hydrocolloids. In an embodiment, the hydrocolloid can constitute between about 10% to about 50% by dry weight of the edible film, preferably about 30% to about 40% by dry weight. The hydrocolloid can be derived from, for example, natural seaweeds, natural seed gum, natural plant exudates, natural fiber extracts, biosynthetic gums, gelatins, biosynthetic process starch or cellulosic materials, alginates, sodium alginate, calcium alginate, carrageenans, guar gum, locust gum, tara gum, gum arabic, ghatti gum, agar gum, xanthan gum, pectin, other like hydrocolloid source material or combinations thereof.

which is in accordance with the content of the *Handbook of hydrocolloids*.

Applicants also wish to point out that while claim terms are normally to be given their ordinary and customary (or plain) meaning (as above), an Applicant may define a claim term in the specification, so that the Applicant is said to be acting as his or her own lexicographer. A definition provided by the Applicant is deemed to override the plain meaning of a term. In this case, however, the Applicant must define the term with "reasonable clarity, deliberateness and precision" and the uncommon definition must be set out in a manner in the disclosure so that a person of ordinary skill in the art would have notice of the change in meaning (see In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994)) (See MPEP § 2111.01(IV))

In the present case, not only does Chen et al. fail to provide a requested uncommon definition with "reasonable clarity, deliberateness and precision", but also gives to "maltodextrin" and to "hydrocolloids", misleading and technically incorrect attributions and meanings which are unwarranted and contrary to the internationally recognized meanings provided by experts in the field.

Therefore, for at least the foregoing reasons, the combination of the limitations in the instant claim is not at all confusing. Thus, the rejection under 35 USC §112, 2nd paragraph has been over and should be withdrawn.

II. PENDING CLAIMS

The presently pending claims are 1-5, 12-14, 16, 17 and 21-24.

III. REJECTIONS UNDER 35 USC §103(a)

In the outstanding Office Action, at page 10 thereof, claims 1, 4, 5, 12, 13, 16 and 17 stand rejected under 35 USC §103(a) as being unpatentable over Chen et al.. This rejection is traversed.

Applicants will demonstrate below that Chen et al., at a minimum, fail to teach or suggest each element of the claimed invention. Furthermore, Chen et al. teach away from the claimed invention. Finally, Chen et al. is also non-analogous art when compared to the claimed invention, such that it should not and cannot be relied upon in fashioning an obviousness rejection.

The Supreme Court in *KSR* confirmed that the *Graham* factor analyses should be used in determining whether a claimed invention is obvious under 35 USC §103(a). Therefore, in the following, the rejected claim, the scope and content of cited art and the differences between the rejected claim and the cited prior art, and explanations as to why these differences are not rendered obvious, are set forth.

Claim 1 is drawn to self-supporting films essentially consisting of:

a) between 40 and 80% by weight of a filmogenic substance consisting of a maltodextrin,

b) between 15 and 55% by weight of a plasticiser,

c) between 0.05% and 30% by weight of an active ingredient for food or pharmaceutical use, on the total weight of said films,

wherein said films are free from hydrocolloids.

Chen et al. disclose (see par [0011] and claim 1):

> 1. A dosage unit comprising a mucosal surface-coat-forming film, wherein the mucosal surface-coat-forming film comprises a water-soluble hydrocolloid, an effective dose of a sexual dysfunction active agent and a mucosal adhesion enhancer, wherein the mucosal adhesion enhancer is a starch graft copolymer.

In the outstanding office Action (pages 5-6), the Examiner himself affirms that:

"Chen et al. teaches a mucosal surface coating forming film containing a water soluble hydrocolloid which includes an effective dose of an active agent (Abstract, [0011]). In an embodiment of the invention, the hydrocolloid includes a polymer consisting of a natural polymer such as a polysaccharide"

"A factor that plays a significant role in determining the properties of the composition is the viscosity of the hydrocolloid [0057]. The hydrocolloid is provided in a range of 5-99% [0058]."

Thus, it should be noted that not only is reliance upon the teaching of Chen et al. about the inclusion of maltodextrin within hydrocolloids ***clearly improper and misplaced***, as demonstrated above, but also the presence of an even high percentage of

hydrocolloids, as expressly acknowledged by the Examiner, is a clear demonstration that this reference fails to teach or suggest each element of the claimed invention.

This also adds to the fact that:

> Chen et al. do not teach a specific embodiment comprised of 40-80% maltodextrin, 15-55% of a plasticizer and 0.05-30% of an active agent.

Indeed, even in the Examiner's view, Chen et al. fail to teach or suggest a single element of the claimed invention.

Assessing the present facts and differences, the obviousness rejection is erroneous because there is no motivation to select and modify the cited art dosage unit to achieve the claimed film free of hydrocolloids, much less with any reasonable expectation of success.

Actually, the Examiner has provided no reasoning or evidence to explain how a dosage unit that can comprise up to 99 wt% of hydrocolloids makes obvious a film free of hydrocolloids. In view of the fact that the Examiner has failed to factually support a *prima facie* case of obviousness, "an applicant is under no obligation to submit evidence of nonobviousness", MPEP §2142.

As noted by the Examiner, "Chen et al. teaches a mucosal surface coating forming film containing a water soluble hydrocolloid which includes an effective dose of an active agent (Abstract, [0011])" and "The hydrocolloid is provided in a range of 5-99% [0058]."

In this regard, ***Chen et al. also teach away*** from the claimed invention because "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the [Applicant]." *Tec Air Inc. vs. Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 1360 (Fed Cir. 1999). See also MPEP §§2141.02 and 2145 (prior art must be considered as a whole, including any disclosure that teaches away from the claimed invention). In this case, a person of ordinary skill, upon reading Chen et al., clearly would be led in a direction divergent from the path that was taken by the Applicants. That a reference teaches away is sufficient on its own to defeat a prima facie case of

obviousness. See *Winner Int'l Royalty Corp. vs. Wang*, 202 F.3d 1340, 1349-50 (Fed Cir. 2000).

Indeed, if Chen et al. dosage unit was modified to exclude hydrocolloids, the modification would render said dosage unit unsatisfactory and inoperable for their intended purpose of overcoming the problems caused by "the mobility of the dosage unit within the mouth." (see par. [0024]): This also counsels against a finding of obviousness. MPEP 2143.01

Finally, if a reference is relied upon in an obviousness rejection, "it must be analogous prior art." MPEP § 2141.01(a). "[A] reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole." Id. Thus, either a reference needs to be in the same field of the claimed invention, or, if the field is not the same, then the reference must logically commend itself to the attention of an inventor of the claimed invention. Characterized in either way, Chen et al are not analogous art.

As already mentioned, Chen et al. concern "dosage units which are not mobile in the mouth because on contact with the moist mucosal surface, the film becomes a coating that adheres to the mucosal surface and then disintegrates and dissolves over a time frame controlled in the design of the dosage." (see par. [0024]) Said dosage unit contains a water soluble hydrocolloid which includes an effective dose of an active agent (Abstract, [0011]). The hydrocolloid is provided in a range of 5-99% [0058]."

None of the disclosed dosage units is given without a hydrocolloid, including all those given in the working Examples (pages 7 to 10), wherein cellulose and their derivatives are preferably used. This is deemed by Chen et al. to allow a user to overcome the above-mentioned problems caused by "the mobility of the dosage unit within the mouth".

It necessarily and unavoidably follows that none of disclosed dosage units are used in the field of Applicants' endeavor of rapidly dissolving self-supporting films

despite being free of hydrocolloids and the Applicants discern no other teaching of Chen et al. that pertain to these purposes. Thus, the Chen et al. invention and disclosure is not in the same field or an analogous field as the claimed invention.

Applicants submit that Chen et al. would not logically commend itself to the attention of the inventors of the claimed invention. Although Chen et al. mention dosage units in the form of films, said units are, however, designed to include hydrocolloids as an essential element in order "to adhere to the mucosal surface and then disintegrate and dissolve over a time frame controlled in the design of the dosage" (see par. [0024]), which is an **effort** that is, not only distinct and unrelated to the purpose of the claimed invention, but is also totally **opposite in direction**, which is the ability of dosage units to ***not be mobile*** in the mouth owing to hydrocolloids.

Because Chen et al. are not analogous art, it cannot and should not be relied upon in an obviousness rejection of Claim 1 and its dependent claims. Accordingly, since claim 1 and the claims dependent thereon distinguish over Chen, the §103(a) rejection has been overcome since the Examiner has failed to establish *prima facie* obviousness by a preponderance of the evidence. Withdrawal of the rejection is accordingly in order and is solicited.

In the outstanding office Action (at page 4), currently pending claim 1 stands rejected under 35 USC §103(a) as being unpatentable over **Barkalow et al.** (US 2004/0096559) in view of **Chen et al.**. This rejection is traversed.

Barkalow et al. concern (see claim 1 and par. [0010]):

"1. An edible thin film product comprising:

a container including a body that defines an interior for housing the edible thin film;

the edible thin film having a characteristic indicative of a flavor of the edible thin film, the characteristic being chosen from the group consisting of color and shape; and

the body including the characteristic."

This serves to solve the problems as set forth at par. [0007] of Barkalow et al., i.e. "providing a confectionery product in a novelty form can enhance the marketability of a product, particularly to young consumers. Edible films could benefit from new, novel forms." This means that the purposes of Barkalow et al. are to make the containers more appealing including providing an edible film.

Applicants will demonstrate below that Barkalow et al. also do not pertain to the same field of endeavour as the claimed invention, thus being a non-analogous art (MPEP § 2141.01(a).)

As already acknowledged by the Examiner in the Office Action, page 6, lines 10-14 and 19-21, the films of Barkalow et al. do not involve any pharmaceutical agent. Exemplary uses of said films are described at pages 7 to 9 of that reference. None of the uses are in the pharmaceutical field and Applicants discern no other teaching of Barkalow et al. that pertain to these uses. Thus, Barkalow et al. invention is not in the same field as the claimed invention.

In addition to the foregoing, Applicants submit that Barkalow et al. would not logically commend itself to the attention of the inventors of the claimed invention. Although Barkalow et al. mention edible films, in said films, however, there is no distinction made among the possible film-formers, so that an exceedingly large number of hydrocolloids are expressly taught as preferred (see par. [0087]). It should be noted that all the given working examples (pages 7 to 9) contain at least one hydrocolloid.

Therefore, the products of Barkalow et al. are designed to enhance the marketability of edible films, particularly to young consumers (see par. [0007]), which is an **effort** that is, not only distinct and unrelated to the purpose of the claimed invention, since **no pharmaceutical agents are involved**, but which is also exactly **opposite in direction**, which is the lack of any distinction being made in the use of maltodextrin and hydrocolloids in films, when only Examples comprising both are given.

Since Barkalow et al. is also non-analogous art, it cannot be relied upon in an obviousness rejection of Claim 1 and its dependent claims. Accordingly, at least for this reason, the claims distinguish over the combination of Barkalow et al. and Chen et al.. Since the rejection is deemed to have been overcome, its withdrawal is solicited.

At least for the fact that it has been demonstrated that both Chen et al. and Barkalow et al. are not analogous art, it follows that the supposed combination of the respective teachings, as provided by the Examiner, is consequently and unambiguously not factually supported and, accordingly, since a *prima facie* rejection for obviousness has not been established by a preponderance of the evidence, the rejection has been overcome and should be withdrawn.

Additionally, because the cited references fail to teach all of the limitations of the claimed invention, one of ordinary skill in the art would not have an apparent reason to combine the references, and, therefore, one would not arrive at the claimed invention. See *KSR,* 127 S. Ct. 1727. An obviousness rejection of the pending claims is also unwarranted for at least this reason.

The foregoing clearly demonstrates that Claim 1 is entirely unobvious over the cited art. If an independent claim is nonobvious under 35 U.S.C. §103(a), then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988); see also M.P.E.P. § 2143.03.

Thus, the § 103(a) rejections of dependent claims 2 and 3 under § 103(a) over the combination of Barkalow et al. and Chen et al. and further in view of Zyck et al. (US 2003/0054039), and of dependent claim 14 over the combination of Barkalow et al. and Chen et al. and further in view of Falkenhausen et al (WO2002/02085), have also been overcome and should be withdrawn.

CONLUSION

In view of the above amendments and the foregoing remarks, Applicants submit that all of the pending claims are in condition for allowance.

The issuance of a Notice of Allowance is respectfully solicited.

Please charge any fees which may be due to our Deposit Account No. 01-0035.

Respectfully submitted,

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